DMH POLICY

Informed Consent for Psychiatric Medications, Electroconvulsive Treatment or Psychosurgery	**Policy # 96-3R** **Date Issued:** February 16, 1996 **Revised Date:** August 22, 1996
Approval by Commissioner **Signed by:** Marylou Sudders	**Effective Date:** September 1, 1996 **Date:** August 22, 1996

I. Purpose

To establish a statewide system for assuring informed consent for psychiatric medications, electroconvulsive treatment and/or psychosurgery and related treatment information.

II. Scope

This policy applies to any entity, be it an individual, program or facility (or any of their staff) that is operated or funded by the Department of Mental Health and the clients (child, adolescent or adult) who receive treatment from them. This policy also applies to any private program or facility that agrees by contract (or other agreement) to comply with this policy.

For clients under the age of 16, it must be understood that each time the policy references "client," it is the parent or legal guardian of the minor client who must be consulted for the purposes of giving informed consent unless the client has been determined to be an emancipated minor (see IV A5). This does not, however, preclude the necessity of involving the minor client in discussions regarding the implications of any recommended treatment.

III. Definitions

A. **Emancipated Minor:** A client under the age of 18 may give consent for medical or dental care if he/she is: married, widowed or divorced; the parent of a child; pregnant or believes herself to be pregnant; a member of the armed forces; living separate and apart from parent or legal guardian and managing his/her own financial affairs.

B. **Authorized Prescribing Clinician**: For the purposes of this document, includes licensed physicians, licensed physician's assistants or licensed clinical nurse specialists practicing in the expanded role, who are authorized under Massachusetts law to prescribe certain kinds of treatment.

C. **Rogers Order**: The judicial review and approval required to treat individuals with antipsychotic medications, electroconvulsive treatment or psychosurgery who are unable to give informed consent.

D. **Treatment:** For the purposes of this document, includes use of psychiatric medications, electroconvulsive treatment and/or psychosurgery.

E**. Competence:** Ability to understand the nature of the illness; the risks, benefits and side effects of the proposed treatments; and capable of rationally manipulating the information to arrive at an informed decision.

IV. Introduction

Although this policy is limited to programs that are operated or funded by DMH, under Massachusetts law, the doctrine of informed consent is applicable to all Authorized Prescribing Clinicians. However, the doctrine of informed consent only extends to clients able to make informed decisions. For those clients incapable of making an informed decision to accept or forego certain forms of treatment, the law provides an alternative means to protect their interests, i.e., appointment of a guardian and application of the doctrine of substituted judgment. In any event, clients who are not able to consent to or refuse treatment shall nevertheless be informed of the purpose, risks, benefits and side effects of the proposed treatment (as provided under this policy) to the extent possible, consistent with the client's ability to understand this information.

There are other circumstances where an incompetent client's right to refuse medication may be overridden to prevent an immediate, substantial and irreversible deterioration of the client's mental illness. Similarly, chemical restraint may be used in an emergency situation pursuant to applicable Department regulations.

A. Consistent with Massachusetts law, the following principles are established with regard to informed consent:

1. For consent to treatment to be informed, it must be voluntary, (i.e., free of coercion), knowing, and competently given. Individuals are presumed competent to make informed decisions.

2. The Authorized Prescribing Clinician owes to the client the duty to disclose, in a reasonable manner, all significant medical information that the Authorized Prescribing Clinician possesses or reasonably should possess that is material to an informed decision by the client as to whether or not to undergo a proposed treatment.

3. Knowing exercise of the right to accept or forego treatment requires knowledge of the available options and risks attendant on each.

4. Competent adults have the right to forego treatment, or even cure, if it entails what, for them, are unacceptable consequences or risks, however unwise their decision may be in the eyes of the medical profession or others.

5. An "emancipated minor" has the same right as an adult to consent to or refuse medical treatment.

6. It is the Department's policy that parents and other legal guardians (for example, DSS if it has custody) of 16 and 17 year old clients should play a central role in the development of the client's treatment plan. The parent(s) or legal guardian(s) should be given the opportunity to be involved in the decision-making and to co-sign the treatment plan unless it is not in the best interests of the 16 or 17 year old client to do so. However, because 16 or 17 years old clients are authorized by law to sign themselves into and out of inpatient mental health facilities, it is the Department's policy to afford these 16 and 17 year old clients the right to consent to and refuse treatment. In order to give informed consent, the 16 or 17 year old client must be capable of understanding the nature of his or her illness and the risks and benefits of the proposed treatment.

In cases where the 16 or 17 year old client refuses treatment, court approval must be obtained before beginning treatment.

Whenever questions arise as to the specific rights of minors, their parent(s) or legal guardian(s), the appropriate DMH legal office should be contacted for clarification.

B. Consistent with acceptable health care practices, facilities and programs covered by this policy shall adhere to standards regarding informed consent established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and identified in its Accreditation Manual for Hospitals, Accreditation Manual for Health Care Networks and Mental Health Manual.

V. Authorized Prescribing Clinician Responsibilities

A. Introduction

Providing information necessary for informed consent is the responsibility of the Authorized Prescribing Clinician. This information shall be provided in the client's own language, in terms the client can understand. The Authorized Prescribing Clinician will discuss the nature of the illness and the need for medication with the client, describing the type of treatment, its risks and benefits, probability of side effects, alternative treatments, and the prognosis with and without any treatment. Further discussion then shall proceed in response to questions that the client has or about specific issues of possible side effects, for example, tardive dyskinesia or certain dystonic reactions from neuroleptic medications. The Authorized Prescribing Clinician assesses the client's ability to understand and process the information and documents this discussion in the medical record.

B. Obtaining Valid Informed Consent

Informed consent must include the following elements:

1. an assessment of the competence/ability of the client to understand that there may be something wrong, that there is a treatment that might help and that the client has the capacity to recognize and report side effects.

2. a description of the condition being treated;

3. an explanation of the proposed treatment;

4. an explanation of the risks, side effects and benefits of the proposed treatment;

5. a set of materials provided to the client that are written in common, everyday language describing the benefits, risks, and side effects of the prescribed medication*;*

6. an explanation of alternatives to the proposed treatment, including not having treatment and the risks, benefits and side effects of the alternatives to the proposed treatment;

7. an explanation of the right to freely consent to or refuse the treatment without coercion, retaliation or punishment. Loss of privileges, threat/use of restraints, discharge, guardianship, Rogers orders or any form of retaliation and/or coercion shall never be used as punishment when a client freely exercises his/her right to refuse/accept treatment. Such interventions may only be utilized in accordance with applicable legal and clinical standards. In cases where a competent client refuses a recommended treatment, alternative, clinically appropriate treatment acceptable to the client, including no treatment, shall be explored and offered where possible.

8. an explanation of the right to withdraw one's consent to treatment, orally or in writing, at any time.

C. Ongoing Communication and Review

When initiating or making substantial changes in treatment for inpatients or outpatients, the discussion of informed consent shall be documented early in the treatment process and periodically as continuing dialogue about it occurs. For stable outpatients, documentation at annual intervals is sufficient, unless there are changes in the treatment or the client's mental and/or physical status. For long stay inpatients, informed consent issues will be documented as part of the periodic review process, at three and six month intervals, and then annually unless there are changes in the treatment or in the client's mental and/or physical status.

Obtaining informed consent is an ongoing process rather than a one-time event. Discussions about informed consent, in particular regarding psychiatric medications, do not stop with the initial consent but continue through the course of treatment as the client experiences the medication and its benefits and side effects and especially when the care of the client is transferred to a new Authorized Prescribing Clinician. If at any point in time a client decides to stop taking the treatment or experiences side effects that were not previously discussed, such discussions shall then take place and be subsequently documented in the medical record as part of the informed consent process.

A continuing assessment of the capability of making informed decisions must also occur, particularly when the Authorized Prescribing Clinician has reason to believe that the client's ability to understand and process the information has changed.

D. Documentation of Informed Consent

Documentation of informed consent in the medical record shall include:

1. an assessment of the client's capacity to understand and process the information;

2. an indication that the client has been provided information including risks, benefits and side effects;

3. notation that the client has assented to, or refused treatment;

4. a signed copy of a consent form, or an indication of the oral consent on the form. These forms shall be duplicate carbonless forms. The client shall be given a signed copy of his or her consent form.

5. a description of any questions and comments offered by the client and the Authorized Prescribing Clinician's response;

6. an ongoing review of the efficacy of treatment, the side effects of medications; alternative treatments and continuing competency; this review should include appropriate diagnostic tests**.** Discussion of all of these shall occur on a regular basis and shall be documented in the medical record.

E. Incompetency, Guardianship or an Order for Psychiatric Treatment under Chapter 123 s. 8B

1. If after conversations between an Authorized Prescribing Clinician and a client, the Authorized Prescribing Clinician has reason to believe that a client is not capable of giving informed consent, this is documented in the medical record describing the specific facts upon which this conclusion is based. The client should be fully and honestly informed of the pursuit of the guardianship, in a manner appropriate to his or her needs. A discussion regarding the process of obtaining guardianship or a court order for treatment in accordance with MGL c. 123 s. 8B shall be initiated with legal counsel. Legal counsel will work with the Authorized Prescribing Clinician to determine whether a petition will be filed, and in which forum, based upon relevant criteria such as the standards set forth in DMH Policy #83-50, an assessment of the merits of the case, resources of the legal office, and other considerations. In addition, if the Authorized Prescribing Clinician has reason to believe that a client under guardianship has been restored to competency, s/he should contact legal counsel for advice.

2. If the client has a legal guardian with responsibility for treatment decisions, the above procedures for informed consent shall be followed with the guardian. It should be noted that if antipsychotic medications, electroconvulsive treatment or psychosurgery are to be given, information should be shared with the guardian, but only the court can give consent to this treatment.

3. Clients who are not able to consent to or refuse treatment shall nevertheless be informed of the purpose, risks and benefits of the proposed treatment (as provided under this policy) to the extent possible, consistent with the client's ability to understand this information.

4. It is the parent or legal guardian of a client under the age of 16 who has the authority to make treatment decisions on behalf of the client, unless the client is an Emancipated Minor. Additionally, see section IV. A. 6 of this policy regarding 16 and 17 year olds.

VI. Treatment Team Responsibilities

A. Treatment teams in conjunction with the client shall assess the best method to provide ongoing information about treatment.

B. Written materials that supply current and accurate explanations of treatment in common, everyday language shall be made available to clients for review and discussion. A copy of these materials shall be given to the client and the client's guardian if s/he has one, and a copy shall be placed in the medical record. At the client's request, a copy will be given to the client's family or significant others designated by the client.

VII. Administrative Responsibilities

A. On inpatient units and in 24-hour residential facilities, a human rights officer shall introduce himself/herself to a client as soon as possible and preferably within 72 hours of admission to inform the client of her/his human rights, including informed consent, and the right to refuse treatment, accept treatment, or request alternative treatments. The human rights officer will also answer any questions or provide additional information if requested to do so.

B. A blank copy of the consent form shall be posted in patient areas of outpatient services and on inpatient units. Information from the most recent edition of the PDR Family Guide to Prescription Drugs, unless at such time another standardized, regularly updated set of fact sheets are adopted by the Department, shall be available at the place of service. These fact sheets shall be translated into languages spoken by the clients, where possible.

C. Settings that prescribe and/or administer medications shall have methods appropriate to client needs to provide ongoing information and education about medication including, but not limited to medication groups.

D. A separate document on Informed Consent Rights shall be posted in patient areas. This posting shall reflect the values and principles embodied in this policy and shall convey that clients have the right to freely consent to or refuse recommended treatment without coercion, retaliation or punishment unless a court has ordered said treatment or in an emergency situation.

The posted document shall read as follows:

You are an active partner in your treatment.

You have the right to know the benefits, risks and side effects of the proposed treatment, alternative treatments and what is likely to occur if you go untreated. This information

should be discussed with you and given to you in the form of a consent form. Information sheets for each prescribed medication also will be given to you.

You are entitled to an explanation of your right to freely consent to or refuse treatment without coercion, retaliation or punishment. Loss of privileges, threat/use of restraints, discharge, guardianship, Rogers Orders or any form of retaliation and/or coercion shall never be used as punishment when you freely exercise your right to refuse/accept treatment. Such interventions may only be utilized in accordance with applicable legal and clinical standards. When you are competent and refuse a recommended treatment, alternative clinically appropriate treatment acceptable to you, including no treatment, shall be explored and offered where possible.

You have the right to freely consent to or refuse recommended treatment unless a court has ordered said treatment. (In emergency situations, medication may be given without your consent.)

If you have not received adequate information about your treatment rights, believe that your rights are being violated, or that you are being coerced into treatment, you may contact: The Human Rights Officer, Mental Health Legal Advisors Committee or other Mental Health Protection and Advocacy agency, etc. (include local methods of access of each).

E. When an inpatient is under guardianship with a Rogers Order from a Probate Court, the order should be sent to the treating outpatient psychiatrist upon discharge along with a copy of the discharge summary. Similarly, when an outpatient under guardianship with a Rogers Order from a Probate Court is admitted to a hospital, a copy of the order should be sent to the inpatient treatment facility. The release of client records and information must be consistent with confidentiality requirements.

VIII. Training and Evaluation

A. The process of informed consent is reviewed at least annually as part of each facility's quality improvement plan.

B. Annually, all Authorized Prescribing Clinicians credentialed to provide services at each facility will be trained regarding the requirements of informed consent. Furthermore, all staff involved in medication delivery, dispensing and education, as well as human rights officers, will also receive this training annually.

IX. Implementation Responsibility

Implementation of this policy, including training and evaluation, shall be the responsibility of the person in charge of each facility or program included under Part II (Scope).

X. Review

This policy shall be reviewed annually.

References:

The following statutes, regulations and policies are applicable to this policy and may be referenced:

MGL c. 111, s. 70E; MGL c. 123, ss. 4, 23, 24 and 25; MGL c. 201**;** 104 CMR. 3.08; 104 CMR 15.06; 104 CMR 3.12; 104 CMR. 16.00; DMH Policy # 83-50